510(k) Summary of Safety and Effectiveness K000171
CBYON, Inc.
Surgical Operating System

Statement of Intended Use:

The CBYON Surgical Operating System is a computer-aided, image-guided system intended for planning and intraoperative navigation for cranial, spinal, and cranial biopsy procedures.

Submitted by:

CBYON, Inc.
2275 E. Bayshore Road
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Telephone: (650) 842-1800
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Contact Person:

Rory Randall
Product Director
Telephone: (650) 842-1811
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Date Summary Prepared:

January 19, 2000

Name of the Device:

Proprietary Name:	CBYON Surgical Operating System (SOS)
Common/Usual Name:	Computer-assisted, image-guided stereotaxic system
Classification Name:	Stereotaxic Instrument (per 21 CFR 882.4560)

Predicate Devices: K000171

The technological characteristics or the CBYON SOS are the same or similar to those found in the predicate devices. The CBYON SOS is substantially equivalent to the following FDA cleared frameless stereotaxic systems:

1. Medtronic Sofamor Danek StealthStation (Neurological) [K983670, K954276] and LandmarX (otorhinolaryngologic) [K974187].

2. Radionics' OTS (neurological and otorhinolaryngologic) [K990632, K974602].

3. BrainLab's VectorVision (neurological and otorhinolaryngologic) [K983831, K962939].

Device Description:

The SOS is a computer-aided, image-guided system intended for planning and intraoperative navigation for surgical procedures related to intracranial and extra-cranial pathology. The SOS provides real-time, three-dimensional visualization and navigation tools for all stages of surgery including preoperative planning, intraoperative navigation, and post-operative validation. The SOS transforms two-dimensional patient images (scan sets), derived from computer tomography (CT) and magnetic resonance imaging (MR), into dynamic, three-dimensional representations. The system performs spatial mapping from one image space to another image space or from image space to physical space allowing the physician to correlate scan sets with each other and to the patient.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 3 2000

Mr. Rory Randall
Product Director
CBYON, Inc.
2275 E. Bayshore, Suite 101
Palo Alto, California 94303

Re: K000171
Trade Name: CBYON Surgical Operating System
Regulatory Class: II
Product Code: HAW
Dated: January 19, 2000
Received: January 20, 2000

Dear Mr. Randall:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Applicant: CBYON, Inc.

510(k) Number (if known): Not Yet Assigned K000171

Device Name: CBYON Surgical Operating System

Indications for Use: The CBYON Surgical Operating System is a computer-aided, image-guided system intended for planning and intraoperative navigation for cranial, spinal, and cranial biopsy procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000171

(Per 21 CFR 801.109)

(Optional Format 1-2-96)